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UV SPECTROPHOTOMETRIC ANALYSIS AND VALIDATION OF BENZOYL PEROXIDE IN SOLID DOSAGE FORM

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ABSTRACT

Objectives: A new, economical, sensitive, simple, rapid UV spectrophotometric method has been developed for the estimation of Benzoyl peroxide in pure form and pharmaceutical formulation. **Method:** This UV method was developed using methanol as a solvent. In the present method the wavelength selected for analysis was 245nm. UV-Visible double beam spectrophotometer (Systronic 2201) was used to carry out spectral analysis. The ICH guidelines were used to validate the method. **Results:** The method was validated for linearity, range, accuracy, precision, robustness, LOD and LOQ. Linearity was found in the range of 5-25µg/ml. Accuracy was performed by using recovery study. The amount of drug recovered was found to be in the range of 100.1-100.5%. The % RSD value was found to be less than 2. **Conclusion:** The proposed UV spectroscopic method was found to be accurate, precise, stable, linear, specific, and simple for quantitative estimation of benzoyl peroxide in bulk and pharmaceutical dosage form. Hence the present UV spectroscopic method is suitable for routine assay of Benzoyl peroxide in bulk and pharmaceutical formulations.

KEYWORDS

Benzoyl peroxide, UV-Visible spectrophotometric method and Method validation.

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INTRODUCTON

One of the most frequently employed techniques in pharmaceutical analysis is UV-Visible spectrophotometry. The amount of ultraviolet or visible radiation absorbed by a substance in a solution is measured by UV spectrophotometer[1].

Benzoyl peroxide used as a medication to treat mild to moderate acne. It has three-fold activity in treating acne. I.e. sebostatic, comedolytic, and inhibits growth of *C. acnes*. Its molecular formula is

$C_{14}H_{10}O_4$. IUPAC name of benzoyl peroxide is benzoyl benzenecarboperoxoate[3] (Figure No.1).

MATERIAL AND METHODS

Instruments

UV/Visible double beam spectrophotometer Systronic 2201. Standard cuvettes having 10mm of path length are used for analysis. Ultrasonicator (microclean-103) was used to sonicate the formulation sample. Drug sample was weighed by using electronic analytical balance (Shimadzu AY220).

Chemicals and reagents

Active pharmaceutical ingredient of Benzoyl peroxide is gifted as a sample from Aadhaar Life Sciences Pvt. Ltd. Solapur. Marketed formulation of Benzoyl peroxide was procured from local pharmacy.

EXPERIMENTAL WORK

Method Development

Preparation of standard stock solution of Benzoyl peroxide

10mg of standard drug Benzoyl peroxide was accurately weighed and transferred into 10ml volumetric flask and sufficient amount of methanol was added into it and sonicated for 15 minutes, finally volume was made up to the mark with the same solvent to make 1000µg/ml stock solution. From this 1ml was again diluted to 10ml to get a concentration of 100µg/ml of Benzoyl peroxide. From 100µg/ml solution 5ml was again diluted to 10ml to get a concentration of 50µg/ml.

Selection of Wavelength

To determine the wavelength for measurement, Benzoyl peroxide (50µg/ml) solution was scanned in the range of 200-400nm against distilled water as blank. Wavelength of maximum absorption was determined for drug. Benzoyl peroxide showed maximum absorption at 245nm.

Assay of benzoyl peroxide gel

1gm of gel was accurately weighed and transferred into 10ml volumetric flask and dissolve in 5ml of acetone. This solution was sonicated for 15 minutes and final volume was made up to the mark with acetone. From this solution 1ml is transferred into 10ml volumetric flask and diluted up to 10ml with acetone. The absorbance of this solution was measured at 245nm.

RESULTS AND DISCUSSION

Method Validation

The method was validated for several parameters like Linearity, Accuracy, Precision, Robustness, Limit of Detection (LOD), Limit of Quantification (LOQ) and Specificity of Benzoyl peroxide[4-7].

Linearity and Range

The linear relation between absorbance and concentration of drug was evaluated using three replicates over concentration range in 5-25µg/ml by making the replicates (Table No.1 and Figure No.3). The wavelength for linearity was scanned at 245nm. By taking five different concentrations for linearity the regression coefficient was found to be 0.9992 i.e. in limit of standard. Hence linearity parameter was found to be validated.

Accuracy

Accuracy of the method was confirmed by recovery studies from marketed formulation at three different levels of standard i.e. 50%, 100%, 150% was done to confirm accuracy of the developed method. The amount of benzoyl peroxide is calculated at each level and percentage recoveries were calculated (Table No.2).

Precision

Precision of the developed method expressed in terms of relative standard deviation of the absorbance. The solution was analyzed in 6 replicates for intra-day precision and in two successive days for inter-day precision. The % RSD value was found to be less than 2. Results confirmed that the precision of the method was found to be accepted. Precision results were given in Table No.3 and Table No.4 for intra and inter-day precision respectively.

For Intra-day and inter-day precision relative standard deviation is in limit i.e. less than 2% hence parameter is validated.

Robustness

Robustness is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its

reliability during normal usage. Robustness was carried out on two different instruments and also carried out by using two different analysts (Table No.5).

By change in concentration and wavelengths i.e. 245nm and 250nm % RSD is less than 2% i.e. within the range. So parameter was validated

Ruggedness

The degree of reproducibility of test results of same sample within different laboratories and different analyst under same condition with same concentration.

By change in analyst and laboratory, there is no effect on absorbance with same conditions (Table No.6). Hence, parameter was validated.

Limit of detection (LOD)

Limit of detection of an individual analytical procedure is the lowest amount of analyte in the sample which can be detected but not necessarily quantitated as an exact value. LOD was found to be 0.862.

Limit of quantitation (LOQ)

Limit of quantitation of an individual analytical procedure is the lowest amount of an analyte in the sample which can be quantified as an exact value. LOQ was found to be 2.612.

Table No.1: Results of Linearity

S.No	Concentration (µg/ml)	Absorbance
1	5	0.134
2	10	0.359
3	15	0.572
4	20	0.789
5	25	0.975

Table No.2: Results of Accuracy

S.No	Name of drug	Recovery levels	Concentration (µg/ml)	Amount recovered	% Recovery with S.D.
1	Benzoyl peroxide	50 %	10	10.001	100.01±0.70
		100 %	20	20.001	100.03±0.13
		150 %	30	30.004	100.05±0.25

Table No.3: Results for Intra-day Precision

S.No	Concentration (µg/ml)	Absorbance
1	10	0.538
2	10	0.539
3	10	0.537
4	10	0.539
5	10	0.537
6	10	0.539
S.D.		0.000983
%RSD		0.182693%

Table No.4: Results for Inter-day precision

S.No	Concentration (µg/ml)	Absorbance (Day1)	Absorbance (Day2)
1	10	0.538	0.537
2	10	0.539	0.538
3	10	0.537	0.539
4	10	0.539	0.538
5	10	0.537	0.537
6	10	0.539	0.539
S.D.		0.000983	0.000894
%RSD		0.182693%	0.16625%

Table No.5: Results for robustness

Wavelength	245nm	250nm
Concentration	12µg/ml	12µg/ml
Absorbance	0.612	0.613
	0.613	0.612
	0.611	0.611
	0.613	0.612
	0.612	0.611
	0.614	0.613
Average	0.613	0.612
S.D.	0.0011	0.00089
% RSD	0.179445	0.145425

Table No.6: Results for ruggedness

S.No	Concentration	Analyst 1	Analyst 2
1	15(µg/ml)	0.764	0.765
		0.762	0.764
		0.765	0.766
		0.764	0.763
		0.766	0.765
		0.765	0.762

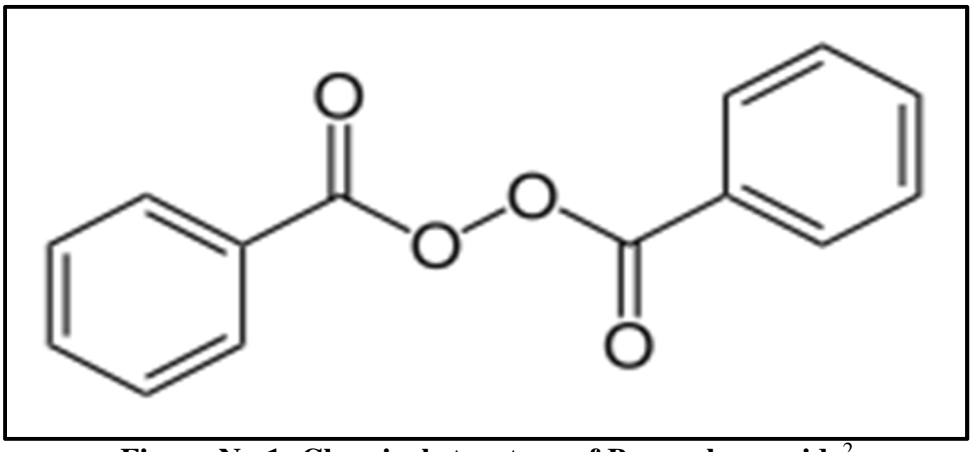

Figure No.1: Chemical structure of Benzoyl peroxide[2]

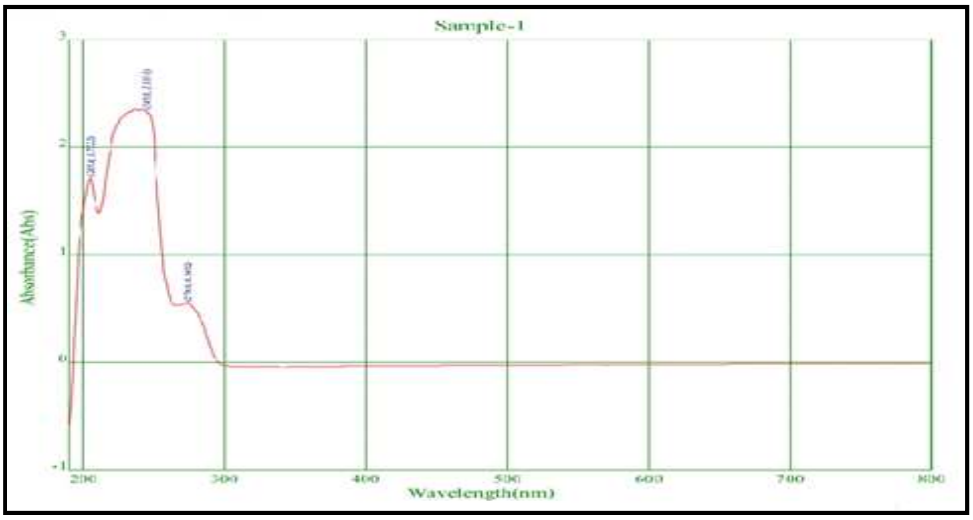

Figure No.2: UV Visible Spectrophotometer Graph

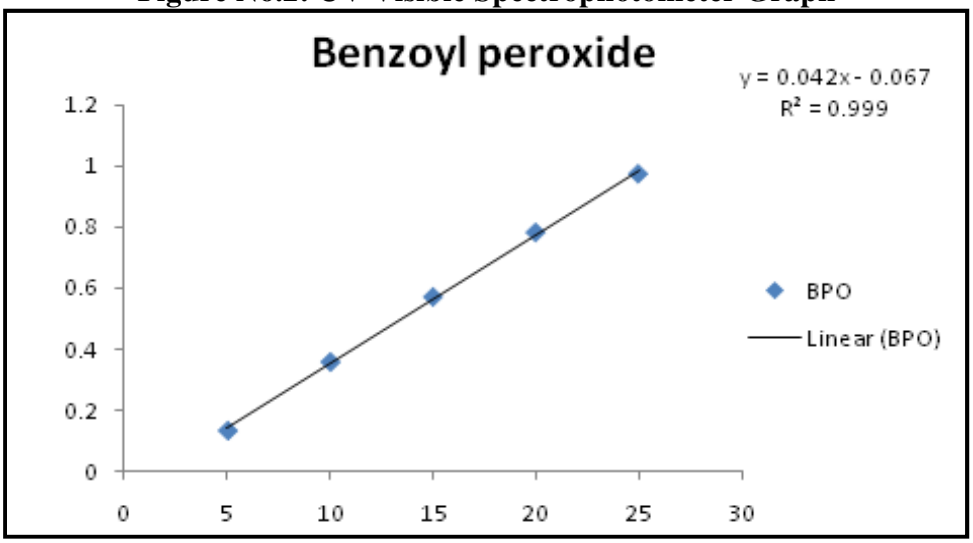

Figure No.3: Calibration curve for Benzoyl peroxide

CONCLUSION

The proposed UV spectroscopic method is found to be accurate, precise, stable, linear, specific, and simple for quantitative estimation of benzoyl peroxide in bulk and pharmaceutical dosage form. Hence the present UV spectroscopic method is suitable for routine assay of benzoyl peroxide in bulk and pharmaceutical formulations.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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